UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOZORB DEVICE PRODUCTS LIABILITY LITIGATION	*	
	*	Civil Action No. 1:22-cv-11895-ADB
This Order Relates To: 1:23-cv-10579-ADB	*	

MEMORANDUM AND ORDER

BURROUGHS, D.J.

Before the Court is Defendant Hologic's motion for summary judgment on Plaintiff Beth Deuel's claim that Hologic's alleged failure to warn her breast-cancer surgeon about the risks associated with BioZorb, a radiographic marking device, caused her to suffer a variety of injuries. [ECF No. 67 ("Motion" or "Mot.")].[1] Deuel, as well as more than eighty other individual plaintiffs spread across twenty-two cases before this Court, alleges that Hologic breached tort and contractual duties in the design and marketing of BioZorb. Deuel is one of four bellwether trial pool plaintiffs.[2] In support of the pending summary judgment motion, Hologic contends that the undisputed facts foreclose any reasonable jury from finding that Hologic's failure to warn about risks associated with BioZorb proximately caused Deuel's injuries. See [ECF No. 68 ("Memorandum" or "Mem.")]. For the following reasons, Hologic's motion is **GRANTED IN PART** and **DENIED IN PART**.

[1] Unless otherwise specified, all citations to the record refer to Civil Action No. 1:23-cv-10579.
[2] See [Case No. 1:22-cv-11895, ECF No. 201].

I. BACKGROUND

A. Factual Background

The BioZorb marker is an implantable medical device approved by the Food and Drug Administration ("FDA") as a Class II medical device indicated for situations where an excision site needs to be marked for future medical procedures, like radiation treatment. See, e.g., [ECF No. 83-1 ("Responsive Statement of Undisputed Facts" or "RSUF") ¶¶ 1–3]. The BioZorb consists of a spiral-shaped bioabsorbable spacer that holds permanent titanium clips. [Id. ¶ 2]. Although BioZorb markers come in a range of sizes, the parties agree that the image below generally depicts an accurate visual representation of the device.

[Id. ¶ 2]. The device is intended to dissolve into the body during a process Hologic calls "resorption," leaving behind titanium clips that allow for radiographic targeting. [Id. ¶ 4].

According to BioZorb's Instructions for Use ("IFU") in effect at the time of Deuel's operation, the resorption process may take "one or more years." [ECF No. 111-1]. Specifically, the IFU advised that "the spacer material retains its functional integrity for approximately [two] months, while complete resorption may require up to one or more years." [Id.] The IFU expressly warns of the following risks and contraindications:

> The Marker should not be placed in a tissue site with clinical evidence of infection . . . . The marker should only be used by

> physicians trained in surgical techniques. The physician is responsible for its proper clinical use. The Marker is shipped sterile; do NOT re-sterilize any portion of the Marker. The Marker is for SINGLE USE only. Do NOT use if the package is open or damaged, or if the temperature indicator has a black center. Use the Marker prior to the expiry date shown on the product label.

[Id.].

Beth Deuel is a citizen of Michigan. [ECF No. 70-2 ("Deuel Dep.") at 17:22–23]. After Deuel received a diagnosis of invasive ductal carcinoma in April 2018, [RSUF ¶ 5]; [ECF No. 82-24 at 19], Dr. Stephen Cahill performed a partial mastectomy and sentinel lymph node biopsy on May 18, 2018, at McLaren Macomb Hospital in Michigan, [RSUF ¶ 6]. During surgery, Dr. Cahill implanted a BioZorb in Deuel's right breast. [Id.] On May 30, 2018, prior to beginning radiation therapy, Deuel underwent a second procedure to remove additional tissue at the lumpectomy site to confirm that all cancerous cells had been removed. [ECF Nos. 70-6, 70-7, 70-8].

In a deposition taken in connection with the instant motion, Deuel testified that after her surgery, she experienced pain, a visible and palpable lump or mass, and cosmetic changes to her breast, which she discussed with her doctors. [Deuel Dep. at 47:10–19, 48:15–19, 72:23–73:2]. By early 2022, her symptoms had worsened, and she testified that on Dr. Cahill's advice, she decided to undergo a third surgery to remove the BioZorb. [Id. at 206:19–22]. The explant procedure took place on May 17, 2022. See [ECF No. 70-1 ("Cahill Dep.") at 97:23–98:13]. Deuel testified that after the removal, her symptoms abated. [Deuel Dep. at 227:19–228:10].

Dr. Cahill, a board-certified general surgeon, was deposed on May 10, 2024. At the time of Deuel's procedure in 2018, Dr. Cahill had been using the BioZorb for between three and five years. [Cahill Dep. at 17:20–18:3]. Dr. Cahill testified that Hologic sales representatives had informed him that the BioZorb would resorb in "three or four months," [id. at 21:4–21:10], but

that "right from the get go," he realized that resorption took longer than that. [Id. at 21:11–14]. By the time he treated Deuel, he was advising patients that the resorption period could be prolonged:

> . . . [B]y 2018, I think we realized that it was not going away in three months, so at that time I was generally saying it's going to be around for a lot longer, how long I do not know. I've seen some patients that it's gone [after] three months, I've seen some it's been a year and I've seen where you think it's still there in three years, so there's something with the metabolism of the individual that kind of impacts how quickly it resorbs, but I wasn't so much concerned with that. I was more concerned that they realize if they felt something in the breast, it was not a cancer.

[Id. at 35:6–17]. He testified that he would have told Deuel that resorption could take an "extended" or "unknown" amount of time. [Id. at 36:6–7]. In sum, based on Dr. Cahill's experience, the potentially indefinite resorption time did not cause complications apart from a persistent, palpable lump, "but if you can explain the lump and you know it's not cancer, it's not so much of a concern." [Id. at 35:22–36:2].

During his deposition, Dr. Cahill also answered questions about an FDA alert published on February 27, 2024 (the "FDA Safety Communication"), see [ECF No. 83-8], concerning "adverse event reports" in patients who had received BioZorb implants. See [Cahill Dep. at 43:2–53:15]. The FDA Safety Communication described complications including infection, fluid buildup, migration, erosion, pain, palpability, and "other complications possibly associated with extended resorption time." [ECF No. 83-8 at 2]. Dr. Cahill was unaware at the time of Deuel's implantation that the listed complications were "specifically related to the BioZorb," but he explained that "a lot of these [complications] would refer to any kind of surgery with any kind of implantable device." [Cahill Dep. at 44:3–5]. For example, he understood the risk of infection associated with BioZorb implantation to be linked to the lumpectomy procedure. [Id. at 44:12–16]. Similarly, he

understood that fluid buildup, also known as seroma, was a risk inherent in "any implantable device," including BioZorb, but that he believed that the risk of "seroma development with the BioZorb was actually less than . . . without the BioZorb" based on his own clinical experience. [Id. at 44:20–24]. By comparison, he testified that he had never seen a patient experience migration or erosion, nor was he otherwise aware of such a risk in 2018. See [id. at 45:12–22].

Deuel's attorney also asked Dr. Cahill whether he would have still implanted the BioZorb in Deuel in 2018 had he known about the risks described in the FDA Safety Communication. [Cahill Dep. at 52:8–11]. Dr. Cahill responded: "Yeah," and that with "any kind of surgery you have to weigh relative risks and benefits." [Id. at 52:13–14]. Further, he believes that "BioZorb presented as a useful tool to achieve an end and I think it still is." [Id. at 52:18–19]. He conceded that "there may be some [patients] that are at greater risk than others," but he ultimately testified that the risk would not have changed his decision to implant the BioZorb in Deuel, [id. at 52:8–24]. On examination by Hologic's attorney, Dr. Cahill clarified that he has continued to implant the BioZorb since learning about the FDA Safety Communication, but he now specifically advises patients of the risks described by FDA and the fact that the government released a warning. [Id. at 138:13–19]. According to his testimony, no patient had declined use of the BioZorb after receiving that information. [Id. at 138:24–139:9].

B. Relevant Procedural History

Deuel and four co-plaintiffs filed this lawsuit against Hologic on March 15, 2023, [ECF No. 1], and amended their complaint twice. [ECF Nos. 104, 111]. The operative complaint asserts four causes of action: Negligence for Failure to Warn (Count I), Negligence for Design Defect (Count II), Breach of Implied Warranty of Merchantability (Count III), and Negligence (Count IV). [ECF No. 111 ("Second Amended Complaint" or "SAC")].

The Court's case management orders allowed phased discovery and summary judgment proceedings. [ECF Nos. 11, 12]. The first phase of discovery is limited to core document discovery and depositions of plaintiffs and their implanting physicians to allow for summary judgment motions limited in scope to the application of the learned-intermediary doctrine to the causation analysis concerning each plaintiff's failure-to-warn claims. See [ECF No. 11]. Accordingly, Hologic filed a motion for summary judgment based on the learned-intermediary doctrine on June 28, 2024. [Mot.; Mem.]. Deuel opposed on August 5, 2024, [ECF No. 83 ("Opposition" or "Opp.")], and Hologic replied on August 23, 2024, [ECF No. 93 ("Reply")].

II. DISCUSSION

A. Legal Standard

A movant may obtain summary judgment only by showing "that there is no genuine dispute" between the parties "as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party must first show "an absence of evidence to support the nonmoving party's case." Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). "This burden can be satisfied in two ways: (1) by submitting affirmative evidence that negates an essential element of the non-moving party's claim or (2) by demonstrating that the non-moving party failed to establish an essential element of its claim." Nantucket Residents Against Turbines v. U.S. Bureau of Ocean Energy Mgmt., 675 F. Supp. 3d 28, 46 (D. Mass. 2023). "The burden then shifts to the nonmovant to establish the existence of a genuine issue of material fact." Pleasantdale, 37 F.4th at 733. The Court must construe "the record and all reasonable inferences therefrom in the light most hospitable" to the nonmoving party. Id. (quoting Houlton Citizens' Coal. v. Town of Houlton, 175 F.3d 178, 184 (1st Cir. 1999)).

Still, the Court will not let cases go to trial based only on a nonmovant's "bald assertions, empty conclusions, or rank conjecture." Hoover v. Hyatt Hotels Corp., 99 F.4th 45, 57 (1st Cir. 2024) (citation and alteration omitted). Instead, where (as here) "the nonmovant bears the ultimate burden of proof" concerning the issue on which summary judgment is sought, the nonmovant "must present definite, competent evidence to rebut the motion for summary judgment." Pleasantdale, 37 F.4th at 733 (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)).

B. Conflict of Laws

Federal courts sitting in diversity jurisdiction apply the forum state's conflict of substantive law rules — here, Massachusetts. Cheng v. Neumann, 106 F.4th 19, 25 (1st Cir. 2024) ("[F]ederal courts sitting in diversity apply the substantive law of the forum state . . . including its conflict of laws rules." (quoting Smith v. Prudential Ins. Co. of Am., 88 F.4th 40, 49 (1st Cir. 2023))). Under Massachusetts conflict-of-laws rules, Michigan law governs Deuel's claims. See Burleigh v. Alfa Laval, Inc., 313 F. Supp. 3d 343, 353–59 (D. Mass. 2018) (describing factors considered under Massachusetts conflict-of-law analysis for products liability claims); In re BioZorb Device Prod. Liab. Litig., Nos. 22-cv-11895, 22-cv-12194, 2024 WL 4309413, at *8–9 (D. Mass. Sept. 26, 2024) (concluding that Burleigh factors weighed in favor of the law of the place of injury). As Deuel testified in her deposition, she has been a resident of Michigan for her entire life, [ECF No. 70-2 ("Deuel Dep.") at 17:22–23], was implanted with the BioZorb device there, and suffered her resulting injuries there, [RSUF ¶ 6]. Thus, the Court will apply Michigan law to her claims. Accord In re BioZorb, 2024 WL 4309413, at *7–9.

C. Count I

To prevail on a failure-to-warn claim under Michigan law, "a plaintiff must prove that: (1) the defendant owed a duty to the plaintiff; (2) the defendant violated that duty; (3) the defendant's breach was a proximate cause of the plaintiff's injuries; and (4) the plaintiff suffered damages." Avendt v. Covidien Inc., 262 F. Supp. 3d 493, 520 (E.D. Mich. 2017) (citing Warner v. Gen. Motors Corp., 357 N.W.2d 689, 694 (Mich. Ct. App. 1984)); see also Glittenberg v. Doughboy Recreational Indus., 491 N.W.2d 208, 214 (Mich. 1992). Indeed, "[a]n indispensable element of a product liability case is proof that the manufacturer's alleged negligence proximately caused the plaintiff's injury." Nichols v. Clare Community Hosp., 476 N.W.2d 493, 496 (Mich. Ct. App. 1991). Michigan "follows the learned intermediary doctrine," and consequently, "adequate warnings" concerning prescription drugs and medical devices "are owed to physicians and surgeons and not to their patients." Avendt, 262 F. Supp. 3d at 521; see also Brown v. Drake-Willock, Int'l, 530 N.W.2d 510, 515 (Mich. Ct. App. 1995). Thus, "[t]o establish the element of proximate causation, a plaintiff must show that an adequate warning would have prevented the plaintiff's injury by altering the prescribing doctor's conduct or that the doctor might have heeded the warning." Nichols, 476 N.W.2d at 496.

The parties agree that because only the causation element is presently before the Court, the sole question to be decided at this point is whether the record creates a genuine dispute of material fact as to whether "an adequate warning would have prevented the plaintiff's injury by altering" Dr. Cahill's decision to implant the BioZorb. [Mem. at 11 (quoting Nichols, 476 N.W.2d at 496)]; [Opp. at 12 n.6 (same)]. A plaintiff cannot demonstrate proximate cause when a doctor's testimony makes clear that "even if additional warnings had been given, the doctor still would have prescribed" the allegedly harmful medical product. Allen v. Owens-Corning

Fiberglas Corp., 571 N.W.2d 530, 535 n.4 (Mich. Ct. App. 1997) (citing Mowery v. Crittenton Hosp., 400 N.W.2d 633, 638 (Mich. Ct. App. 1986)). Nor can an alleged failure to warn be the proximate cause of a patient's injuries if her "physician [was] aware of the risk of a prescription drug [or device] but still prescribes it for a patient." In re Zyprexa Prod. Liab. Litig., No. 1:04-md-01596, 2009 WL 2163118, at *15 (E.D.N.Y. July 13, 2009) (applying Michigan law and citing cases). Michigan law places the burden on the plaintiff to produce or otherwise identify in the record evidence that "the doctor might have heeded the warning." Nichols, 476 N.W.2d. at 496.

Here, Dr. Cahill testified that he would have implanted the BioZorb in Deuel even if he had known about the complications listed in the FDA Safety Communication. [Cahill Dep. at 52:13, 52:24]. The FDA Safety Communication included warnings about the complications that Deuel specifically suffered: infection, seroma, and pain, resulting in a need for further procedures. [ECF No. 83-8]. Dr. Cahill also testified that, at the time of his deposition, he still used the BioZorb in treating other patients. [Cahill Dep. at 18:4–8]. The Court agrees with Hologic that this testimony is sufficient to satisfy its threshold burden at summary judgment. If undisputed, this testimony would preclude a jury from finding that Hologic's alleged failure to warn proximately caused Deuel's injuries because the testimony indicates that "even if additional warnings had been given, [Dr. Cahill] still would have" used the BioZorb. Allen, 571 N.W.2d at 535 n.4.

Deuel's proof fails on causation. She contends that summary judgment should be denied by pointing to contradictory evidence in the record about whether Dr. Cahill was already aware of the risks of the BioZorb at the time he prescribed it. See [Opp. at 12 n.6 ("Dr. Cahill testified that he was unaware of these risks.")]; [RSUF ¶ 31]. This testimony alone, however, cannot

defeat summary judgment, as Dr. Cahill's awareness of the risks or lack thereof at the time he implanted the device into Deuel says nothing about the critical question on the issue of causation: that is, what Dr. Cahill would have done if he had known of those risks. Moreover, Deuel has cited no authority under Michigan law for why the lack of such knowledge, standing alone, provides a basis to deny summary judgment here. Cf., e.g., Zyprexa, 2009 WL 2163118, at *16–17 (granting summary judgment on failure-to-warn claim under Michigan law where treating physician was aware of complication risk at the time of treatment). Consequently, she has "fail[ed] to make a showing sufficient to establish the existence of an element essential to [her] case, and on which [she] will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Summary judgment as to Count I is **GRANTED**.

D. Counts II, III, and IV

Hologic further contends that Deuel has inadequately pleaded her second count, a design-defect claim, by, among other things, failing to identify any "specific defects in the design of BioZorb." See [Mem. at 1–2]. These arguments are unrelated to the learned-intermediary doctrine, and therefore, they fall outside the limited scope of the summary judgment filings permitted at this stage under the Court's case management orders. In any event, as the Court allowed the plaintiffs in these cases to amend their design defect claims and Hologic to file a separate motion to dismiss, which is now fully briefed, see [Case No. 1:22-cv-11895, ECF Nos. 190–91, 193, 200], the Court hereby **DENIES** without prejudice Hologic's motion for summary judgment as to Deuel's design-defect claim.

To the extent Hologic seeks summary judgment on Counts III and IV based on the learned-intermediary doctrine, summary judgment is **GRANTED IN PART,** to the extent such

claims are premised on a failure to warn and **DENIED IN PART**, to the extent such claims are premised on a design defect theory of liability. See In re BioZorb, 2024 WL 4309413, at *14.

III. CONCLUSION

For the foregoing reasons, the motion is **GRANTED IN PART** and **DENIED IN PART**.

SO ORDERED.

February 3, 2025

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE